(iv) Lactose content, maximum 60 percent—as determined by the methods prescribed in section 16.057 (liquid sample), entitled ''Gravimetric Method—Official Final Action'' under the heading ''Lactose,'' or in section 31.061 (dry sample), entitled ''Lane-Eynon General Volumetric Method'' under the heading ''Lactose—Chemical Methods—Official Final Action.''

(v) Moisture content, 1 to 6 percent—as determined by the methods prescribed in section 16.192, entitled ''Moisture (41)—Official Final Action'' under the heading ''Dried Milk, Nonfat Dry Milk, and Malted Milk.''

(vi) Solids content, variable—as determined by the methods prescribed in section 16.032, entitled ''Method I—Official Final Action'' under the heading ''Total Solids.''

(vii) Titratable Acidity, variable—as determined by the methods prescribed in section 16.023, entitled ''Acidity (2)—Official Final Action'' under the heading ''Milk,'' or by an equivalent potentiometric method.

(2) Limits of impurities are:

Heavy metals (as lead). Not more than 10 parts per million (0.001 percent), as determined by the method described in the Food Chemicals Codex, 3d ed. (1981), pp. 512–513,[2] which is incorporated by reference.

(3) The whey protein concentrate shall be derived from milk that has been pasteurized, or the whey protein concentrate shall be subjected to pasteurization techniques or its equivalent before use in food.

(c) The whey protein concentrate may be used in food in accordance with good manufacturing practice as indicated in § 184.1(b)(1).

(d) The percent of protein present on a dry product basis, i.e., ''whey protein concentrate (____% protein)'', shall be declared on the label of the package sold to food manufacturers. The percent of protein may be declared in 5-percent increments, expressed as a multiple of 5, not greater than the actual percentage of protein in the product, or as an actual percentage provided that an analysis of the product on which the actual percentage is based is supplied to the food manufacturer.

(e) The presence of whey protein concentrate in a finished food product shall be listed as ''whey protein concentrate''.

[46 FR 44441, Sept. 4, 1981, as amended at 54 FR 24899, June 12, 1989]

§ 184.1983 Bakers yeast extract.

(a) Bakers yeast extract is the food ingredient resulting from concentration of the solubles of mechanically ruptured cells of a selected strain of yeast, *Saccharomyces cerevisiae.* It may be concentrated or dried.

(b) The ingredient meets the following specifications on a dry weight basis: Less than 0.4 part per million (ppm) arsenic, 0.13 ppm cadmium, 0.2 ppm lead, 0.05 ppm mercury, 0.09 ppm selenium, and 10 ppm zinc.

(c) The viable microbial content of the finished ingredient as a concentrate or dry material is:

(1) Less than 10,000 organisms/gram by aerobic plate count.

(2) Less than 10 yeasts and molds/gram.

(3) Negative for *Salmonella, E. coli,* coagulase positive *Staphylococci, Clostridium perfringens, Clostridium botulinum,* or any other recognized microbial pathogen or any harmful microbial toxin.

(d) The ingredient is used as a flavoring agent and adjuvant as defined in § 170.3(o)(12) of this chapter at a level not to exceed 5 percent in food.

(e) This regulation is issued prior to general evaluation of use of this ingredient in order to affirm as GRAS the specific use named.

§ 184.1984 Zein.

(a) Zein (CAS Reg. No. 9010–66–6) is one of the components of corn gluten. It is produced commercially by extraction from corn gluten with alkaline aqueous isopropyl alcohol containing sodium hydroxide. The extract is then cooled, which causes the zein to precipitate.

(b) FDA is developing food-grade specifications for zein in cooperation with the National Academy of

[2] Copies may be obtained from the National Academy of Sciences, 2101 Constitution Ave. NW, Washington, DC 20037, or examined at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.